An Update from the Office of Public Health Preparedness

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Outline

- Description of OPHP
- New Federal initiative to states
- Laboratory strategy for BT
- Field testing for BT

“The events of the fall”

- Letters containing extremely pure anthrax sent through the mail
- About 25 cases with 5 deaths
- Mixed messages even within HHS - e.g. treatment for anthrax
  - CDC used ciprofloxacin
  - NIH said tetracycline
  - FDA raised licensing issues
- Secretary Thompson asked DA Henderson to consult and form advisory committee
- Events required more rapid mobilization

HHS changes since Sept. 11

- Nov. 1 - HHS Sec'y appointed DA Henderson head of new Office of Public Health Preparedness (OPHP)
- Nov. 26 - Phil Russell and I joined office working on vaccine and lab/science issues respectively. Jerry Hauer is lead for emergency response. Mike Osterholm is "our man at CDC"
- Dec. 18 - charter of office signed with ground rules
- May 3rd - Jerry Hauer to Director - DA back to advisor

The “usual suspects”

Anthrax as a Biological Weapon
Medical and Public Health Management

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Donald A. Henderson, MD, MPH
John G. Bartlett, MD
Michael S. Ascher, MD
Edward Eitzen, MD, MPH
Arthur M. Friedlander, MD
Jerome Hauer, MPH
Joseph McDade, PhD
Michael T. Osterholm, PhD, MPH

Objective To develop consensus-based recommendations for measures to be taken by medical and public health professionals following the use of anthrax as a biological weapon against a civilian population.

Participants The working group included 21 representatives from staff of major academic medical centers and research, government, military, public health, and emergency management institutions and agencies.

Evidence MEDLINE databases were searched from January 1966 to April 1998, using the Medical Subject Headings *anthrax*, *Bacillus anthracis*, *biological weapon*, *biological terrorism*, *biological warfare*, and *biowarfare*. Review of references identified by this search led to identification of relevant references published prior to 1966. In addition, participants identified other unpublished references and sources.

JAMA 1999;281:1735-1745 (May 12, 1999)

Office of Public Health Preparedness

- Ground rules for OPHP

- HHS is Federal lead for medical and public health preparedness for bioterrorism and other public health emergencies
  - Integration of HHS elements at OPHP
  - OPHP is single Point of Contact for other departments - a “one department model”
  - OPHP to direct all efforts of HHS - CDC, NIH, FDA, OEP, HRSA, etc.
  - OPHP is lead in planning and in determining funding (c.f. “coordinate” - OHS)

Office of Public Health Preparedness

- Mandate is broad:
  - Preparedness for bioterrorism, emerging infectious diseases, other infectious disease outbreaks, and other public health emergencies
  - True “dual use”
  - Strong elements of accountability and performance measurements
  - Primary emphasis on biological threat agents
  - Primary priority is State and local preparedness

Office of Public Health Preparedness

- OPHP funding - ~$3.1B DOD supplemental in Feb.
  - $2B for internal HHS programs
    - Infectious disease surveillance - CDC
    - National pharmaceutical stockpile - CDC
    - Smallpox/anthrax vaccine procurement - HHS
    - Basic and applied research - NIH
    - Laboratory infrastructure - NIH
  - $1B for State and local support (vs. $75M)
    - $120M for biological laboratories (vs. $8M)
    - $135M for hospital planning (vs. $0)

State grant focus areas

- A – Preparedness Planning and Readiness Assessment
  - (NEW) Local stockpile distribution plan
- B – Surveillance and Epidemiology Capacity
- C – Laboratory Capacity - Biological
- D – Laboratory Capacity - Chemical
- E – Health Alert Network/Communication and IT
- (NEW) F – Risk Communication and Health Information
- (NEW) G – Education and Training

- Hospital funding under HRSA

- April 15 due date - six week turnaround for CDC/HRSA and OPHP review

- Public announcement last Thursday in New York City

The Laboratory Response to Bioterrorism

How do we approach this?

- Central facility - "bricks and mortar"
  - –Slow turnaround
  - –Where to build it?
- Federal partners (Military)
  - –Not diagnostic labs
  - –Not in mission - space constraints
- Distributed network - public health labs
  - –Existing infrastructure - decayed
  - +Rapid turnaround
  - +Direct connection with epidemiology
  - +"Routine" methods for these labs

Premises for PH laboratory network

- All threat diseases occur naturally in U.S. (CA)
  - Botulism, plague, anthrax, tularemia, "pox"
  - Brucella, burkholderia, cholera, Q fever
- Public health laboratories are responsible
- Frequency of disease low - impact is high
- Frequency of testing not low
- "Classical" microbiology works well

"Classical" bacteriology

- Gram stain
- Culture on selective media
- Colony morphology
- Heat shock
- Confirmation
  - Phage, direct fluorescence, agglutination

"Classical" virology

- Isolation in cell culture
- Inoculation into animals
- Direct fluorescence
- Electron microscopy

Bioterrorism PH laboratory network
Levels of performance

- Level A - culture only
  - Clinical and small PH labs - thousands
- Level B - first level confirmation
  - Major county and small state PH labs - about 110
- Level C - high capacity confirmation / containment
  - Major state PH labs - about 10
- Level D - research and development
  - Federal and private partners (PHS, DOD, NL, industry)

Field testing
for
biological agents

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- Hand-held assays ("smart tickets", "tiles")
  - Based on antibody-capture (70's technology)
  - Sensitivity poor (10^5 to 10^8 for anthrax)
  - Specificity using household items not determined
  - Confounded by “near neighbors” or killed organisms
  - False-positives in field use (including the military)
  - Can't use in decision-making

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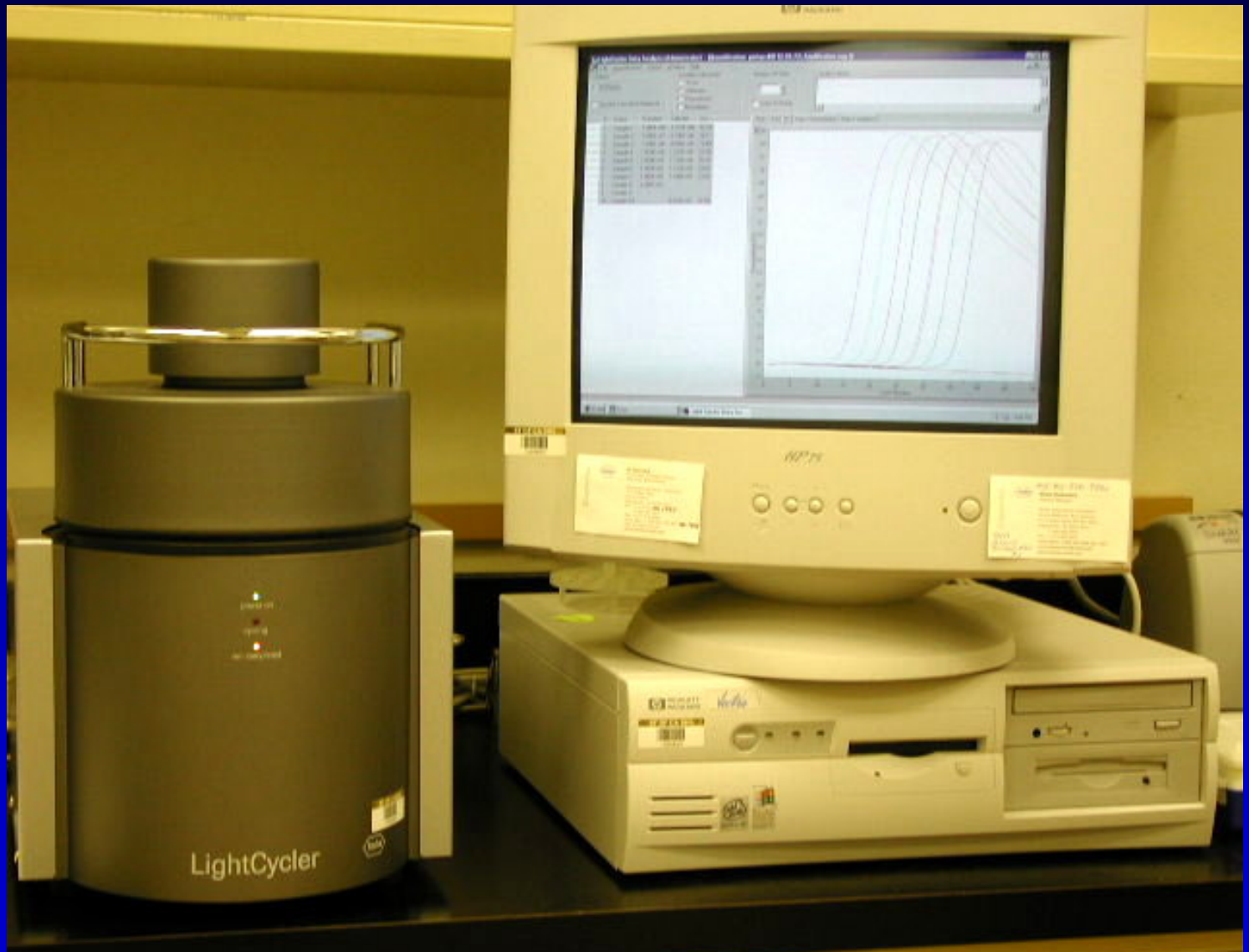
  - Can't use in decision-making
- Release was premature - chemical mindset driven
- Network will evaluate and qualify, if possible
- Recent study confirms anecdotal reports
- We do not recommend that they be used - public statement soon

Polymerase chain reaction (PCR)

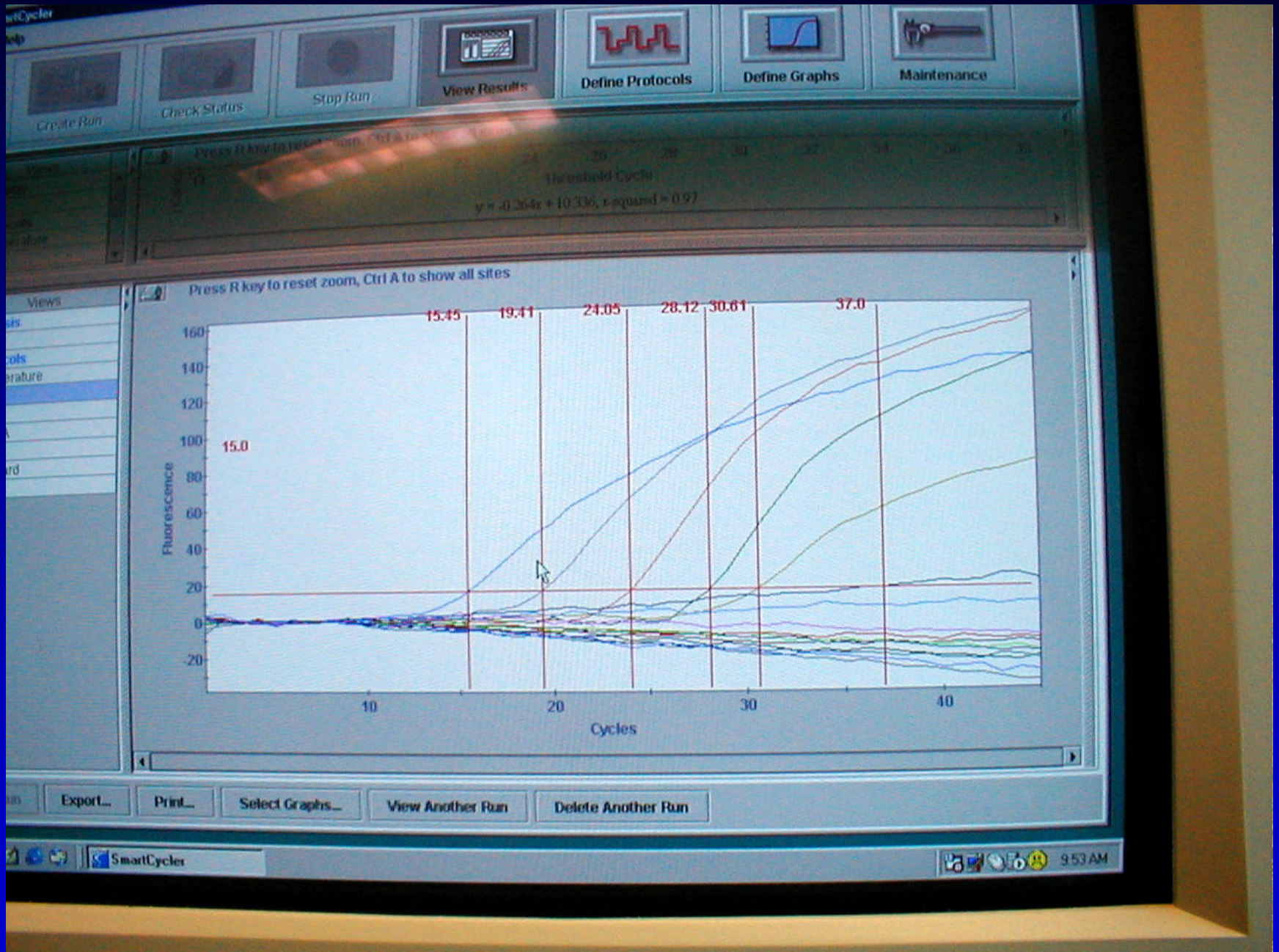
- Amplifies microbial nucleic acid
- Requires extraction and chemical treatment prior to instrument
- Pre-analytic phase prone to contamination
- Numerous stories of false-positives
- Technology deployed to LRN under tight supervision
- Closed systems being developed

Smart Cycler

LightCycler (AKA Rapid)



Smart Cycler



What is status of PCR?

- Introduced into network labs for anthrax, plague and tularemia - coming for smallpox
- Role in testing for anthrax unclear since New York City experience showed far lower sensitivity than culture for anthrax --> stopped using it
- Is anthrax a special case - probably

- False-positive tests at Federal Reserve, World Bank and IMF based on PCR testing of irradiated mail
- Interagency discussion on standards and protocols

Field testing for biological agents

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- But you are not left high and dry. Contact and get to know your nearest LRN laboratory - they are prepared to help.
- Correct answers are more important than instant ones. There is enough time to wait for the right answer.

Questions?